

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 15, 1997 list were made in March, 1997

### New Approvals

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**ANADA No.: 200-188**

Pioneer Product: 132-338  
Trade Name : Betagen™ Topical Spray  
Ingredients: Gentamicin sulfate, betamethasone valerate  
Sponsor: Med-Pharmex, Inc.  
Approval Date: 01/29/97  
Status: Prescription Only  
Route: Topical  
Species: Canine  
Drug Form: Spray  
Concentration: Gentamicin base: 0.57 mg/mL; betamethasone: 0.284 mg/mL  
Indications: For the treatment of infected superficial lesions in dogs caused by bacteria sensitive to gentamicin.

21CFR 524.1044f

**NADA No.: 141-011**

Trade Name : Denagard 10 + Chlortetracycline Premixes  
Ingredients: Tiamulin hydrogen fumarate, chlortetracycline hydrochloride  
Sponsor: Fermenta Animal Health Co.  
Approval Date: 08/20/96  
Status: Over-the-counter  
Route: Oral  
Species: Porcine  
Drug Form: Premixes  
Concentration: Tiamulin: 35 g/ton in Type C Medicated Feed  
Chlortetracycline: 400 g/ton in Type C Medicated Feed  
Indications: For the control of swine dysentery associated with *Serpulina (Treponema) hyodysenteriae* susceptible to tiamulin and for treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* sensitive to chlortetracycline and treatment of pneumonia caused by *Pasteurella multocida* sensitive to chlortetracycline.  
Tolerance: 21CFR 556.738: 0.6 ppm for 8-alpha-hydroxymutilin (marker compound) in liver (target tissue) of swine.  
21CFR 556.150: Chlortetracycline: 12 ppm in kidney, 6 ppm in liver, 2 ppm in muscle, and 12 ppm in fat.  
Withdrawal: 2 days  
Patent No.: 4278674 Expiration date: 07/14/98  
Exclusivity: 3 years

21CFR 556.738, 558.128, 558.600

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### NADA No.: 141-059

Trade Name : BMD Premix and CTC Premix  
Ingredients: Bacitracin methylene disalicylate, chlortetracycline hydrochloride  
Sponsor: Alpharma Inc.  
Approval Date: 09/18/96  
Status: Over-the-counter  
Route: Oral  
Species: Porcine  
Drug Form: Type A Medicated Articles to prepare a Type C Medicated Feed  
Concentration: BMD: 10-30 g/ton; CTC: 400 g/ton  
Indications: BMD: for increased rate of weight gain and improved feed efficiency.  
CTC: for the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.  
Tolerance : 21CFR556.670: BMD: 0.5 ppm negligible residue in uncooked edible tissues.  
21CFR556.150: CTC: 4 ppm in uncooked kidney, 2 ppm in uncooked liver, 1 ppm in uncooked muscle, 0.2 ppm in uncooked fat.  
Withdrawal: Zero days  
21CFR 558.128, 558.76

### NADA No.: 141-062

Trade Name : Program Cat Flavor Tabs  
Ingredients: Lufenuron  
Sponsor: Ciba-Geigy Animal Health, Ciba-Geigy Corp.  
Approval Date: 03/03/97  
Status: Over-the-counter  
Route: Oral  
Species: Feline  
Drug Form: Tablets  
Concentration: 135 mg and 270 mg/tablet  
Indications: For use in cats and kittens, six weeks or older, for the control of flea populations.  
Exclusivity: 3 years  
21CFR 520.1288

## Supplemental Approvals

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### NADA No.: 141-025

Trade Name : Cattlyst  
Ingredients: Laidlomycin propionate potassium  
Sponsor: Hoffman-La Roche, Inc.  
Approval Date: 03/05/97  
Status: Over-the-counter  
Route: Oral  
Species: Bovine (cattle fed in confinement for slaughter)  
Drug Form: Type A Medicated Article  
Concentration: 100-2,000 g/ton  
Indications: For increased rate of weight gain and improved feed efficiency.  
Tolerance: Not established

This supplemental application provides for the use of dry Laidlomycin propionate potassium Type A article for making liquid Type B Medicated Feeds used in the preparation of dry Type C Medicated Feeds.  
21CFR 558.305

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### **NADA No.: 141-018**

Trade Name : Saraflox Injection  
Ingredients: Sarafloxacin hydrochloride  
Sponsor: Abbott Laboratories  
Approval Date: 01/21/96  
Status: Prescription Only  
Route: In ovo  
Species: Embryonated broiler eggs  
Drug Form: Liquid (solution)  
Concentration: 50 mg/mL  
Indications: For the control of early chick mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.  
Withdrawal: Not required  
Patent No.: 4,730,000      Expiration date: 03/18/2005  
Exclusivity: 3 years

This supplemental application provides for the use of sarafloxacin hydrochloride in 18-day embryonated broiler eggs for the control of early chick mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin. The product was previously approved for the control of early mortality in day-old broiler chickens associated with *E. coli* organisms susceptible to sarafloxacin.

21CFR 522.2095

### **NADA No.: 141-035**

Trade Name : Program Cat Tablets  
Ingredients: Lufenuron  
Sponsor: Ciba-Geigy Animal Health, Ciba-Geigy Corp.  
Approval Date: 01/23/97  
Status: Over-the-counter  
Route: Oral  
Species: Feline  
Drug Form: Tablets  
Concentration: 90 mg and 204.9 mg/tablet  
Indications: For use in cats and kittens, six weeks or older, for the control of flea populations.  
Exclusivity : 3 years

This supplemental application provides for expanding the indications to include the control of flea populations in cats at a minimum dose of 30 mg/kg. The product is approved for the prevention and control of flea populations in dogs.

21CFR 520.1288

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**NADA No.:** 140-833

Trade Name : Ivomec Plus  
Ingredients: Ivermectin, clorsulon  
Sponsor: Merck Research Laboratories, Div. of Merck & Co., Inc.  
Approval Date: 02/24/97  
Status: Over-the-counter  
Route: Subcutaneous  
Species: Bovine  
Drug Form: Liquid  
Concentration: Ivermectin: 10 mg/mL; clorsulon: 100 mg/mL  
Indications: For the effective treatment and control of the following parasites of cattle:  
Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi* (including inhibited *O. ostertagi*), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Bunostomum phlebotomum*, *Nematodirus helvetianus* (adults only), and *N. spathiger*.  
Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus*.  
Liver Flukes: *Fasciola hepatica* (adults only).  
Cattle Grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum*.  
Sucking Lice: *Linognathus vituli*, *Haematopinus eurysternus*, and *Selenopotes capillatus*.  
Mites (Scabies): *Psoroptes ovis* (syn. *P. communis* var. *bovis*) *Sarcoptes scabiei* var. *bovis*.  
For control of infections of *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment; and *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment in cattle.  
Tolerance: 21CFR556.344: Ivermectin: 100 ppb in liver (target tissue).  
21CFR556.163: Clorsulon: 1 ppm in kidney.  
Withdrawal: 49 days  
Patent No.: 4199569 Exp. date: 04/22/97  
Exclusivity: 3 years

This supplemental application provides for persistent control of gastrointestinal roundworms and lungworms following use of ivermectin and clorsulon injection for cattle.

21CFR 522.1193

**NADA No.:** 097-452

Trade Name : Oxyject 100  
Ingredients: Oxytetracycline HCl  
Sponsor: Boehringer Ingelheim Animal Health, Inc.  
Approval Date: 02/21/97  
Status: Over-the-counter  
Route: Subcutaneous, intravenous, intramuscular  
Species: Bovine, porcine  
Drug Form: Liquid (solution)  
Concentration: 100 mg/mL  
Indications: For the treatment of the following disease conditions associated with one or more of the oxytetracycline pathogens listed as follows:  
Beef cattle and non-lactating dairy cattle: pneumonia and shipping fever complex due to *Pasteurella* sp., *Hemophilus* sp., and *Klebsiella* sp. susceptible to oxytetracycline.  
Swine: bacterial enteritis (scours, colibacillosis), pneumonia, leptospirosis due to *Escherichia coli*, *Pasteurella multocida* or *Leptospira pomona*.  
In sows as an aid in control of porcine colibacillosis (baby pig scours) due to *Escherichia coli*.

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Tolerance: 21CFR 556.500: 12 ppm in kidney.  
Withdrawal: Cattle subcutaneous: 2 days  
Cattle and swine intramuscular or intravenous: 13 days  
Exclusivity: 3 years

This supplemental application provides for the addition of the subcutaneous route in cattle, with a withdrawal period of 2 days, and a withdrawal period for intramuscular and intravenous routes of 13 days in cattle. This application also set the new tolerances to the approved product Oxyject 100.

*21CFR 522.1662a*

**NADA No.: 095-735**

Trade Name : Rumensin  
Ingredients: Monensin sodium  
Sponsor: Elanco Animal Health, a Division of Eli Lilly and Co.  
Approval Date: 02/06/97  
Status: Over-the-counter  
Route: Oral  
Species: Bovine, caprine  
Drug Form: Type A medicated article  
Concentration: 90.7 g/lb  
Indications: For increased rate of weight gain

This supplemental application provides for use of a 90.7 grams per pound (200 g/kg) monensin Type A medicated article for making Type B and C medicated cattle and goat feeds. The supplemental approval is for a higher use of Type A article.

*21CFR 558.355*

**NADA No.: 034-254**

Trade Name : MGA 100/200 Premix  
Ingredients: Melengestrol acetate  
Sponsor: Pharmacia & Upjohn Co.  
Approval Date: 02/18/97  
Status: Over-the-counter  
Route: Oral  
Species: Bovine (heifers intended for breeding)  
Drug Form: Dry premix  
Concentration: 100 and 200 mg/lb  
Indications: Heifers fed in confinement for slaughter: for increased rate of weight gain, improved feed efficiency and suppression of estrus (heat). Heifers intended for breeding: for suppression of estrus (heat).  
Tolerance: 21CFR 556.380: 25 ppb for residues of the parent compound, melengestrol acetate, in fat of cattle.  
Exclusivity: 3 years

This supplemental application provides for the use of melengestrol acetate (MGA) in heifers intended for breeding for suppression of estrus (heat).

*21CFR 558.342*

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### **NADA No.: 039-402**

Trade Name : MGA Liquid Premix  
Ingredients: Melengestrol acetate  
Sponsor: Pharmacia & Upjohn Co.  
Approval Date: 02/18/97  
Status: Over-the-counter  
Route: Oral  
Species: Bovine (heifers intended for breeding)  
Drug Form: Liquid premix  
Concentration: 500 mg/lb  
Indications: Heifers fed in confinement for slaughter: for increased rate of weight gain, improved feed efficiency and suppression of estrus (heat).  
Tolerance: 21CFR 556.380: 25 ppb for residues of the parent compound, melengestrol acetate, in fat of cattle.  
Exclusivity: 3 years

This supplemental application provides for the use of melengestrol acetate (MGA) in heifers intended for breeding for suppression of estrus (heat).

*21CFR 558.342*

### **NADA No.: 128-686**

Trade Name : Bio-Cox  
Ingredients: Salinomycin sodium  
Sponsor: Hoffmann-La Roche, Inc.  
Approval Date: 02/03/97  
Status: Over-the-counter  
Route: Oral  
Species: Broiler, roaster, and replacement (breeder and layer) chickens and quail  
Drug Form: Type A Medicated Article to produce a Type C Medicated Feed  
Concentration: Type A: 30 g/lb; Type C: 0.02-0.03 g/lb  
Indications: For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.  
Tolerance: The safe concentration of total salinomycin residues in uncooked edible tissues of broiler chickens were established at 0.6 ppm in muscle, 1.8 ppm in liver, and 1.2 ppm in skin/fat. An upper limit of unchanged salinomycin in skin/fat is established at 200 ppb.  
Withdrawal: Zero days  
Exclusivity: 3 years

This supplemental application provides for the use of a 30-gram-per-pound salinomycin Type A article (as salinomycin sodium) to make Type C roaster and replacement (breeder and layer) chicken feeds containing 40 to 60 grams per ton salinomycin sodium activity. The product is approved for use as an anticoccidial for the prevention of coccidiosis in broiler chickens. This supplement provides for the addition of roasters and replacement (breeder and layer) chickens to the approved labeling.

*21CFR 558.550*

### **NADA No.: 095-735**

Trade Name : Rumensin  
Ingredients: Monensin sodium  
Sponsor: Elanco Animal Health, a Division of Eli Lilly and Co.  
Approval Date: 03/26/97  
Status: Over-the-counter  
Route: Oral  
Species: Bovine (slaughter, stocker, feeder, and dairy and beef replacement heifers)

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Drug Form: Type A Medicated Article  
Concentration: 1,620 g/ton of Type C medicated feed  
Indications: For increased rate of weight gain

This supplemental application provides for use of monensin Type A medicated articles to make a revised formulation of a free-choice Type C medicated feed.

21CFR 558.355

### NADA No.: 128-409

Trade Name : Ivomec  
Ingredients: Ivermectin  
Sponsor: Merck & Co., Inc.  
Approval Date: 02/24/97  
Status: Over-the-counter  
Route: Subcutaneous  
Species: Bovine, porcine, reindeer  
Drug Form: Liquid  
Concentration: 10 mg/mL  
Indications: Bovine: for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mite  
Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi* (including inhibited *O. ostertagi*), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T.colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Bunostomum phlebotomum*, *Nematodirus helvetianus* (adults only), and *N. spathiger* (adults only).  
Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus*.  
Cattle Grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum*.  
Sucking lice: *Linognathus vituli*, *Haematopinus eurytetrus*, and *Selenopotes capillatus*.  
Swine: for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites:  
Gastrointestinal roundworms: large roundworm, *Ascaris suum* (adults and 4th stage larvae); red stomach worm, *Hyostrophylus rubidus* (adults and 4th stage larvae); nodular worm, *Oesophagostomum* spp. (adults and 4th stage larvae); threadworm, *Strongyloides ransomi* (adults).  
Somatic roundworm larvae: threadworm, *Strongyloides ransomi* (somatic larvae). Sows must be treated at least 7 days before farrowing to prevent infection of piglets.  
Lungworms: *Metastrongylus* spp. (adults).  
Lice: *Haematopinus suis*.  
Mange mites: *Sarcoptes scabiei* var. *suis*.  
Reindeer: for the treatment and control of warbles (*Oedemagena tarandi*).  
Additional indications contained in this supplemental NADA are for control of infections of *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment, and *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment in cattle.  
Tolerance: 21CFR 556.344: 100 ppb for the marker residue (22,23-dihydro-ivermectin B1a) in cattle. Reindeer: 15 ppb in liver (target tissue). Swine: 20 ppb in liver (target tissue).  
Withdrawal: Cattle: 35 days. Reindeer: 56 days. Swine: 18 days  
Patent No.: 4199569 Expiration date: 04/22/1997  
Exclusivity: 3 years

21CFR 522.1192

## Actions Taken by FDA Center for Veterinary Medicine

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### Change of Sponsor

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**NADA No.:**           **065-492**

From Biocraft Laboratories, Inc. to:  
Teva Pharmaceuticals USA  
Drug labeler code: 000093

**NADA No.:**           **065-495**

From Biocraft Laboratories, Inc. to:  
Teva Pharmaceuticals USA  
Drug labeler code: 000093

**NADA No.:**           **091-668**

From TRINADA, Inc. to:  
Alpharma, Inc.  
Drug labeler code: 046573

**NADA No.:**           **097-452**

From Fermenta Animal Health Co. to:  
Boehringer Ingelhiem Animal Health, Inc.  
Drug labeler code: 000010

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### Withdrawals

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**NADA No.:**           **006-776**

Trade Name:   Sul-Q-Nox  
Sponsor:       I.D. Russell Co. Laboratories  
Date:           03/24/97

**NADA No.:**           **042-489**

Trade Name:   Pro Mix T Medicated/Medi-Flex T Tylan Premix  
Sponsor:       Land O'Lakes, Inc.  
Date:           04/02/97

**NADA No.:**           **098-156**

Trade Name:   Tylan-Sulfa 10-10 Premix/Medi-Flex T:S  
Sponsor:       Land O'Lakes, Inc.  
Date:           04/02/97

**NADA No. :**           **118-874**

Trade Name:   Pyrantel Tartrate Ton Pack  
Sponsor :       ADM Animal Health and Nutrition Div.  
Date:           04/02/97

## Actions Taken by FDA Center for Veterinary Medicine

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**NADA No.:**           **127-825**

Trade Name:    Music City Hygromix 0.6 Premix  
Sponsor :       Music City Supplement Co.  
Date:            04/02/97

**NADA No.:**           **127-826**

Trade Name:    Tylan Sulfa  
Sponsor :       Music City Supplement Co.  
Date:            04/02/97

### Suitability Petition Action

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Number.:        97P-0072 CP1  
Sponsor:        Vetrepharm Research, Inc.  
Petition:        Request permission to file an ANADA for a generic new animal drug, Butequine Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Coopers Animal Health, NADA 116-087 by the following characteristics:  
                    Butequine Paste: 20 g of phenylbutazone per 60 mL syringe of paste (1 g/3 mL).  
                    Butazolidin Paste (pioneer): 12 g of phenylbutazone per 60 g syringe of paste (1 g/5g). The dosage (1-2 g of phenylbutazone/500 lbs body weight) is the same in both products. However, in the generic product, the dosage would be given as 3-6 mL as opposed to 5-10 g of the pioneer product.  
Action:          Filed on 02/25/97.

### Correction of a Final Rule

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The Final rule published in the Federal Register of July 10, 1996, (Green Book update of August, 1996) concerning the approval of a supplemental application for ANADA 200-008 is corrected to reflect that the supplemental approval was granted 3 years marketing exclusivity for the new use. The rule also failed to specify that only Boehringer Ingelheim's oxytetracycline injection is approved for subcutaneous use in cattle.

The following five supplemental NADA applications were approved on July, 1996 and published in the August update of the Green Book: 48-761, 92-286, 92-287, 46-699, 48-480, and 135-935. Certain limitations were not included in the document. These limitations are: "do not feed ducks producing eggs for human consumption"; "feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb/day"; the phrase "cattle (under 700 lb)" must be replaced by "beef cattle".

### Correction to the January 1, 1997 list of the Green Book

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CLTC 10, 20, 30, 50, 70 sponsored by Pfizer, Inc. is wrongly listed as NADA 098-286. The correct number for this NADA is 092-286.